

sively by modifying the composition and properties of the first liquid and the second liquid during controlled particle formation. These parameters, in addition to judicious execution of the post-processing steps, were similarly employed to manipulate the particle composition, component distribution, and surface properties. In the case of particle formulations containing monoclonal antibodies, physiochemical analyses indicated agent activity was substantially preserved immediately following processing and on stability under thermal stress (7 days at 40° C.). Suspension formulations based on the particles exhibited low viscosity at high agent loading in addition to favorable dispersibility properties. The bio-burden was low on account of sterility measures.

INCORPORATION BY REFERENCE

[0524] All publications and patents mentioned herein, are hereby incorporated by reference in their entirety as if each individual publication or patent was specifically and individually indicated to be incorporated by reference. In case of conflict, the present application, including any definitions herein, will control.

EQUIVALENTS

[0525] While specific aspects and embodiments of the subject disclosure have been discussed, the above specification is illustrative and not restrictive. Many variations of the disclosure will become apparent to those skilled in the art upon review of this specification and the claims below. The full scope of the disclosure should be determined by reference to the claims, along with their full scope of equivalents, and the specification, along with such variations.

What is claimed is:

1. A particle comprising at least one therapeutic biologic, wherein the particle comprises less than about 25% internal void space and the circularity of the particle is from about 0.80 to about 1.00, and the particle has a diameter of about 0.1 to about 100 μm .

2. The particle of claim 1, wherein the therapeutic biologic is an antibody or a fragment thereof.

3. The particle of claim 2, wherein the antibody or fragment thereof in the particle has an activity per unit of about 0.5 to about 1.0.

4. The particle of claim 1, wherein the particle comprises less than about 10% internal void space.

5. The particle of claim 1, wherein the particle comprises less than about 5% internal void space.

6. The particle of claim 1, wherein the particle comprises less than about 1% internal void space.

7. The particle of claim 1, wherein the particle has a diameter between about 10 μm to about 50 μm .

8. The particle of claim 1, wherein the particle has a diameter of about 20 μm to about 40 μm .

9. The particle of claim 1, further comprising a carbohydrate, a pH adjusting agent, a salt, a chelator, a mineral, a polymer, a surfactant, a protein stabilizer, an emulsifier, an antiseptic, an amino acid, an antioxidant, a protein, an organic solvent, a paraben, a bactericide, a fungicide, a vitamin, a preservative, a nutrient media, an oligopeptide, a biologic excipient, a chemical excipient, or a combination thereof.

10. The particle of claim 2, wherein the particle has less than about 10% aggregation of the antibody or a fragment thereof.

11. The particle of claim 2, wherein the particle has less than about 10% fragmentation of the antibody or a fragment thereof.

12. The particle of claim 1, wherein the particle has less than about 5% residual moisture by weight.

13. The particle of claim 1, wherein the particle has less than about 3% residual moisture by weight.

14. The particle of claim 1, wherein the particle has less than about 1% residual moisture by weight.

15. The particle of claim 2, wherein the particle has greater than about 70% antibody or a fragment thereof by weight.

16. The particle of claim 2, wherein the particle has greater than about 80% antibody or a fragment thereof by weight.

17. The particle of claim 2, wherein the particle has greater than about 90% antibody or a fragment thereof by weight.

18. The particle of claim 2, wherein the particle has greater than about 95% antibody or a fragment thereof by weight.

* * * * *